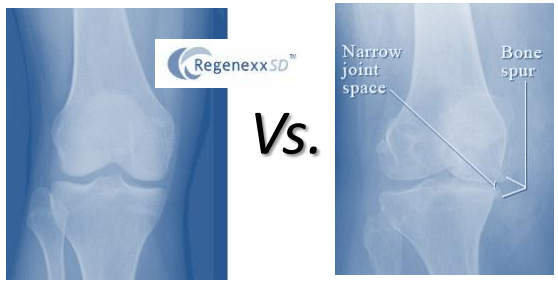
Does Knee Arthritis Severity Impact Regenexx-SD Outcome?

Data Collection

This data is based on our advanced treatment registry which collects outcome information as patients are treated. In particular, it doesn't generalize to all knee stem cell procedures (only Regenexx-SD). Our biostatistician queried our database for Regenexx knee patients vs. their initial candidacy grade (Good, Fair, Poor) which is based on the severity of their arthritis. Good is equivalent to Kellgren-Lawrence (KL) grade 1-2 (mild arthritis), Fair=KL grade 3 (moderate arthritis), Poor= KL grade 4 (severe arthritis).



Caution! This is registry data, which is not the same as a drug company style controlled trial.

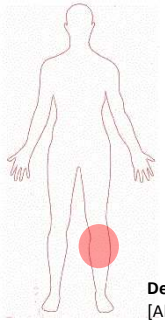
Summary

- ***On earlier analysis (2012) of fewer knee patients, trends emerged that roughly followed established candidacy grading (i.e. patients with more arthritis were less likely to respond favorably).***
- ***However, as the patient numbers in the registry increased (2013), it became clear that the severity of the arthritis was no longer associated with outcome (i.e. patients with more severe arthritis had as much improvement as those with mild arthritis).***

Does the severity of your arthritis matter?

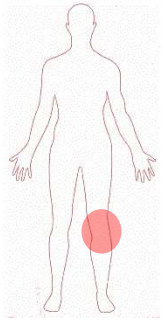
What does this mean?

The Good, Fair, and Poor candidate patients are shown with their percentage improvement at various times after the procedure. If the more severe patients were not responding as well, the green line (Poor-more severe arthritis) would always be on the bottom and the blue line (Good-mild arthritis) on top. There is no statistical difference between the outcome between the grades at these times. Hence, arthritis severity doesn't predict outcome with Regenexx-SD.



What does this mean?

The percentage of patients reporting more than 25% improvement are shown for each severity grade (Good, Fair, Poor). Note that if severe arthritis patients fared worse than the mild arthritis patients, we would expect the green bars to be consistently lower (fewer patients that did well) than the blue bars at each time after the procedure. This is not the case.



Details For Both Charts: The y-axis is percentage Likert improvements queried at the time points noted on the x-axis. [Above left]-Using ANOVA analysis, the differences were significant only at the first month post-treatment (P-value = 0.054) toward "fair" group achieving higher improvement with mean of 46.8 (±29) compared to 33.7 (±38.7) for "good" group and 34.4 (±38.9) for "poor" group. The differences recorded at 3 months and later were not statistically significant. N's for each group were for Good/Fair/Poor at 1 month-80/73/35, 3 months-67/61/22, 6 months-67/52/25, and 12 months-44/44/16. [Above right]-Subjects who reported more than 25% percent improvement were considered as "improvement cases". Subjects who reported 25% or less were considered as "no improvement cases". Candidacy grades (severity) were examined regarding these outcomes (improvement vs. no improvement). Differences at first month post-treatment were statistical significant (P-value = 0.049). Fair grade achieved better improvement rate (72.6%) compared to good grade (55%) and poor grade (54.2%). The differences at subsequent months were statistically non-significant. Total n's for each group out of which the percentage of improved were calculated were Good/Fair/Poor at 1 month-80/73/35, 3 months-67/61/22, 6 months-67/52/25, 12 months-44/44/15.

RegenexxSD™

The Regenexx-SD procedure is a same day bone marrow stem cell procedure that isolates the fractions of bone marrow that have the most stem cells.